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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,280	06/16/2006	Charles L. Sawyers	58086-232451 (2003-279-2)	2639
26694	7590	11/29/2010	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			AEDER, SEAN E	
			ART UNIT	PAPER NUMBER
			1642	
			MAIL DATE	DELIVERY MODE
			11/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,280	Applicant(s) SAWYERS ET AL.	
	Examiner SEAN E. AEDER	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-10 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,10 and 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,9 and 20-28 is/are rejected.
- 7) ☒ Claim(s) 23 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/10 has been entered.

Claims 1, 5-10, and 16-28 are pending.

Claims 6, 8, 10, and 16-19 have been withdrawn.

Claims 1, 5, and 28 have been amended by Applicant.

Claims 1, 5, 7, 9, and 20-28 are currently under consideration.

This Office Action contains New Rejections.

Rejections Withdrawn

All previous rejections are withdrawn.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1642

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 20-22, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnstein et al (Molecular and Cellular Endocrinology, 1995, 115: 177-186).

Burnstein et al teaches a method comprising contacting androgen with LNCaP cells transfected with a CMV-driven expression vector encoding androgen receptor and determining a difference in expression of androgen receptor by comparing androgen-mediated down regulation of androgen receptor with expression of androgen receptor in control LNCaP cells to which androgen has not been administered (see right column of page 179, in particular). Burnstein et al further teaches androgen decreases androgen receptor protein mRNA levels (see right column of page 179, in particular), which would lead to a decrease in androgen receptor protein levels.

As acknowledged by pages 10-11 of the Reply of 7/2/10, LNCaP cells transfected with androgen receptor are inherently hormone refractory.

Although Burnstein et al does not specifically teach the transfected androgen receptor mRNA is expressed 2-5 times higher than “a hormone-sensitive prostate cancer cell” or that androgen induces cellular degradation pathways, dissociates androgen receptor from heat shock proteins, or indirectly targets EGF receptors, the claimed method appears to be the same as the prior art, absent a showing of unobvious differences. The claims do not recite levels of androgen receptor mRNA of required of “a hormone-sensitive prostate cancer cell”. Further, decreases in androgen receptor can be caused by cellular degradation pathways, dissociation of androgen receptor from

Art Unit: 1642

heat shock proteins, and by indirectly targeting EGF receptors. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the method of the prior art does not possess the same material, structural and steps-like characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed method is different from that taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2nd 1992 (PTO Bd. Pat. App. & Int. 1989).

Claims 5, 7, 9, and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Zajchowski et al (Cancer Research, 1993, 53: 5004-5011).

Zajchowski et al teaches a method comprising producing ligand refractory cells by stably transfecting and selecting hormone sensitive MCF-7 breast cancer cells with an exogenous estrogen receptor polynucleotide resulting in an increased level of mRNA encoding said estrogen receptor as compared to parental MCF-7 cells and (a) determining that said increased level of mRNA in said cell is at least two-fold higher than the endogenous amount of estrogen receptor in parental MCF-7 cells, (b) contacting estrogen with the selected transfected cells, (c) examining growth of the treated cells, (d) determining growth of the treated cells, (e) examining growth of control cells that are the same as the selected cells (see pages 5008-5009 and Figure 5, in particular).

Objections

Claims 23 and 27 are objected to for being dependent upon a rejected claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642

Application/Control Number: 10/583,280
Art Unit: 1642

Page 6